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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,006	08/26/2003	Daniel A. Gamache	2427	6056

7590 06/30/2005

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/650,006	GAMACHE, DANIEL A.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☒ Claim(s) *1 and 7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/05,03/04,02/04*, 09/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

10.0

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: the phrase "mtiogen-activated" in line five is believed to be misspelled, and should be "mitogen-activated". Appropriate correction is required.

Claim 7 is objected to because of the following informalities: use of the word "is" in line two renders the claim grammatically confusing. Amendment to a phrase such as "stem from" or the like would clarify the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112 2nd ¶

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: not known, however, the phrase "amide,acetate salt" is unclear, since it is not apparent whether the compound necessarily includes the latter two terms, is a salt thereof, or otherwise. Appropriate correction or explanation is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, and 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Gamache et al. (US 6,696,453 B2).

Gamache et al. teach a method of treating dry eye using a cytokine synthesis inhibitor, namely "2-chloro..." (see Applicant's claim 3 also), with an effective amount of 0.001-1.0% (w/v), topically, as well as treating dry eye associated with refractive surgery (claims 1-5, entire document).

The applied reference has a common inventor (Gamache) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Pflugfelder et al. (US 6,153,607).

Pflugfelder et al. teach a method of treating dry eye using a cytokine synthesis inhibitor, namely an IL-1β synthesis inhibitor (methylprednisolone, in part because of its anti-inflammatory properties), topically (col. 2, lines 32-33).

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Basbaum et al. (US 2002/0151491).

Basbaum et al. teach a method of treating dry eye (para. 35), using a cytokine synthesis inhibitor, namely p38 MAP kinase inhibitors (abstract).

Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Graczyk et al. (US 2004/0235864).

Graczyk et al. teach a method of treating dry eye (e.g. also called Sjogren's syndrome, para. 120), using a cytokine synthesis inhibitor, namely c-Jun N-terminal kinase inhibitors (abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Pflugfelder et al. (US 6,153,607), in view of de Juan (US 5,980,929).

Pflugfelder et al. et al. is discussed above. Although the reference teaches treating dry eye generally and that inflammation is associated therewith (col. 2, lines 27-40), the reference does not expressly teach treating the dry eye specifically associated with refractive (i.e. lasik) surgery (Applicant's claim 5). Additionally, although the references teaches administration is to be administered in any conventional manner (col. 3, lines 14-16), the references does not expressly teach administering the inhibitor in the present range (Applicant's claim 5).

de Juan teach a method of treating the eyes to reduce inflammation following refractive surgery, using protein tyrosine kinase inhibitors (a cytokine synthesis inhibitor)(abstract, col. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat dry eye associated with refractive surgery in Pflugfelder et al., because de Juan teach the advantageous use of related cytokine synthesis inhibitor protein tyrosine kinase inhibitors for inhibiting inflammation following refractive surgery, and because Pflugfelder et al. teach that dry eye is readily associated with inflammation and that treating dry eye involves treating the underlying inflammation. One of ordinary skill in the art would be motivated to combine the teachings of Pflugfelder et al. with de Juan to administer a cytokine synthesis inhibitor for dry eye associated with refractory surgery, because the former teach that dry eye is caused, in part, by inflammation and the latter's recognition of this throughout..

Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any therapeutic effective amount, including 0.001-1.0% (w/w), of the cytokine synthesis inhibitor in Pflugfelder et al., because Pflugfelder et al. teach the advantageous use of the same topically and that it be administered in any conventional manner. One of ordinary skill in the art would be motivated to arrive at the present range, or specific

amounts therein, simply by routine optimization taking into consideration the patient in question and the other factors impacting treatment.

[It is noted that there was no motivation found in the references Basbaum et al. (US 2002/0151491) or Graczyk et al. (US 2004/0235864), to make the same motivational arguments and rejections over Applicant's claims 5-7, since neither reference expressly taught that the cytokine synthesis inhibitor be administered topically].

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 3, and 5-7 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5 of prior U.S. Patent No. 6,696,453 B2. This is a double patenting rejection. The patent is discussed above under § 102(e).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, 06/22/2005

CHRISTOPHER R. TATE
PRIMARY EXAMINER